CLAIMS

We claim:

1. A solution for intravenous administration comprising:

amiodarone, as an active ingredient, solubilized to a concentration range of from 0.2 to 6 mg/ml. in a solution of water for injection and a non-ionic surfactant;

optionally, an osmotic agent; and

wherein the solution requires no dilution before administering and has a pH within the range of from about 2.9 to about 3.2.

2. The solution of Claim 1 wherein the osmotic agent is selected from the group consisting of dextrose, mannitol, sorbitol, glycerol, amino acids such as glycine, and salts such as sodium chloride.

3. The solution of Claim 1 wherein the quantity of non-ionic surfactant is in the range of from about 0.4 to about 12 mg/ml.

4. The solution of Claim 3 wherein the non-ionic surfactant is selected from the group consisting of an ethoxylated polysorbate such as polysorbate 80, an ethylene oxide/propylene oxide copolymer, a polyethoxylated castor oil, and a polyethylene glycol hydroxystearate such as SOLUTOL® HS-15.

5. The solution of Claim 4 wherein the non-ionic surfactant is polysorbate 80.

6. The solution of Claim 4 wherein the non-ionic surfactant is a polyethylene glycol hydroxystearate.

7. The solution of Claim 1 wherein the pH of the solution is about 3.1.

8. The solution of Claim 2 wherein the pH of the solution is about 3.1.

9. The solution of Claim 3 wherein the pH of the solution is about 3.1.

10. The solution of Claim 4 wherein the pH of the solution is about 3.1.

11. A solution for intravenous administration comprising:

amiodarone, as an active ingredient, solubilized to a concentration range of from 0.2 to 6 mg/ml. in a solution of water for injection and a non-ionic surfactant;

optionally, an osmotic agent; and

wherein the solution is a sterilized premix.

12. The solution of Claim 11 wherein the pH of the sterilized premix is in the range of from about 2.9 to about 3.2.

13. The solution of Claim 12 wherein the pH of the sterilized premix is about 3.1.

14. The solution of Claim 11 wherein the sterilized premix is refrigerated.

15. The solution of Claim 14 wherein the sterilized premix is maintained at a temperature within the range of from 3 to about 10°C.

16. A solution for intravenous administration comprising:

amiodarone, as an active ingredient, solubilized in a solution of water for injection and a non-ionic surfactant and wherein the solution requires no dilution before administering and has a drug degradation over time of less than 3% per year at room temperature.

17. The solution of Claim 16 wherein the pH of the solution is within the range of from about 2.9 to about 3.2.

18. The solution of Claim 17 wherein the pH of the solution is about 3.1.

19. A solution for intravenous administration comprising:

amiodarone, as an active ingredient, solubilized to a concentration range of from 0.2 to 6 mg/ml. in a solution of water for injection and a non-ionic surfactant;

optionally, an osmotic agent; and

wherein the solution requires no dilution before administering and has a rate of total impurity formation of less than about 0.02% (w/v) total impurities/week at room temperature.

20. The solution of Claim 19 wherein the pH of the solution is about 3.1.

21. The solution of Claim 19 wherein the osmotic agent is selected from the group consisting of dextrose, mannitol, sorbitol, glycerol, amino acids such as glycine, and salts such as sodium chloride.

22. The solution of Claim 19 wherein the quantity of non-ionic surfactant is in the range of from about 0.4 to about 12 mg/ml.

23. The solution of Claim 22 wherein the non-ionic surfactant is selected from the group consisting of an ethoxylated polysorbate such as polysorbate 80, an ethylene oxide/propylene oxide copolymer, a polyethoxylated castor oil, and a polyethylene glycol hydroxystearate such as SOLUTOL® HS-15.

24. A solution for intravenous administration comprising:

amiodarone, as an active ingredient, solubilized to a concentration range of from 0.2 to 6 mg/ml. in a solution of water for injection and a non-ionic surfactant;

optionally, an osmotic agent; and

wherein the solution requires no dilution before administering and has a drug adsorption of less than 3% in a plastic container which has a plastic surface area to solution volume ratio of approximately 4 cm^{-1} at room temperature.

25. The solution of Claim 24 wherein the pH of the solution is about 3.1.

26. A solution for intravenous administration consisting of:

amiodarone, as an active ingredient, solubilized to a concentration range of from 0.2 to 6 mg/ml. in a solution of water for injection and about 0.4 - 12 mg/ml of a non-ionic surfactant;

optionally, an osmotic agent; and

wherein the solution has a pH within the range of from about 2.9 to about 3.2.

27. The solution of Claim 26 wherein the pH of the solution is about 3.1.

28. The solution of Claim 27 wherein the osmotic agent is selected from the group consisting of dextrose, mannitol, sorbitol, glycerol, amino acids such as glycine, and salts such as sodium chloride.

29. The solution of Claim 27 wherein the non-ionic surfactant is selected from the group consisting of an ethoxylated polysorbate such as polysorbate 80, an ethylene oxide/propylene oxide copolymer, a polyethoxylated castor oil, and a polyethylene glycol hydroxystearate such as SOLUTOL® HS-15.

30. A solution for intravenous administration comprising:

amiodarone, as an active ingredient, solubilized to a concentration range of from 0.2 to 6 mg/ml. in a solution of water for injection and a non-ionic surfactant;

optionally, an osmotic agent; and

wherein the solution requires no dilution before administering and has minimal insoluble particle formation in a plastic container at room temperature.

31. The solution of Claim 30 wherein the pH of the solution is about 3.1.

32. A method for producing an amiodarone solution suitable for intravenous administration comprising the steps of:

(1) providing, as an active ingredient, an effective amount of an amiodarone solution;

(2) solubilizing the active ingredient in a water/surfactant solution to create a aqueous solution;

(3) diluting and cooling the aqueous solution;

(4) adjusting the pH of the aqueous solution with a suitable pH adjuster to an initial pH within the range of from about 2.9 to about 3.2;

(5) further diluting the aqueous solution to the final active ingredient concentration; and

(6) filling suitable containers with the solution.

33. The method of Claim 32 and further comprising the step of mixing into the solution an osmotic agent.

34. The method of Claim 33 wherein the osmotic agent is selected from the group consisting of dextrose, mannitol, sorbitol, glycerol, amino acids, inorganic salts, and any combination thereof

35. The method of Claim 32 and further comprising the step of sterilizing the solution either before or after the filling step, by any suitable sterilization method.

36. The method of Claim 32 wherein the pH of the solution is adjusted to about 3.1.